

Remarks

In the Office Action dated September 9, 2003, the claims have been restricted as follows.

Claims 78-80 and 83-84 constitute Group I. It is classified as being drawn to a method of producing protein encoded by an endogenous gene by introducing a vector comprising a transcriptional regulatory sequence in a cell. Group II is directed to claims 85-91 and 95, characterized as being drawn to a method of screening for expression of a gene which has been activated by introducing a vector comprising a transcriptional regulatory sequence in a cell.

The Examiner asserts that the inventions in Groups I and II are patentably distinct. The Examiner asserts that the methods are materially different because they use different steps. Applicants point out that all of the method claims in both groups have the following steps in common: a vector that comprises a transcriptional regulatory sequence is introduced into a cell, the vector is allowed to integrate into the genome of the cell, an endogenous gene in the cell is activated by the integrated vector, and protein is expressed from the endogenous gene. Accordingly, the steps for producing proteins are essentially the same in both groups of claims. Thus, the only difference between the claims in Groups I and II with respect to steps in the method is that the claims in Group II comprise one additional step: screening for expression. Because this is the case, Applicants assert that even if the claims are considered to be materially different methods, the burden of search will not be increased if the Groups are examined together. The search for art related to the methods of Group II will inherently cover the search

Appl. No.: 09/760,897

Amtd. Dated: September 24, 2003

Reply to Office Action of: September 9, 2003

for the methods of Group I. Thus, Applicants request that the inventions of Groups I and II be rejoined.

Applicants have discussed this restriction requirement, generally, with the restriction expert in the U.S. Patent and Trademark Office, Jim Housel, on September 30, 2003. Mr. Housel pointed out to Applicants' attorney, Anne Brown, that Groups I and II were related as a combination and subcombination and that, if claims to the combination were allowable, then claims to the subcombination would also be allowable. For this reason alone, Applicants request that the claims of Group II be rejoined to the claims of Group I if the claims of Group I are examined.

Claims 92-94 and 96-97, Group III, are characterized as being directed to a cell expressing a protein, the cell comprising integrated into its genome a vector containing a transcriptional regulatory sequence. The Examiner asserts that the invention of Group III is patentably distinct from the inventions of Groups I and II because the invention of Group III can be *used* in either the process of Group I or the process of Group II. The reasoning is that these are materially different processes; therefore, the invention of Group III is distinct from the invention of Group I or II.

Applicants point out that the claims of Group I are not related to the claims of Group III as a product and method of using that product. Applicants take the position that the claims of Group I are actually methods of making the cell of Group III. Thus, the claims are related as a product and method for making that product. It is correct that the preamble is directed to a

method for producing protein but, in fact, the steps of the method are those that result in the claimed cell. Restriction in this case is proper if the product could be made by a materially different process. In this case, the claimed product is integrally related to the process. A cell expressing a protein which is activated by integration of a transcriptional regulatory sequence cannot be made except by integrating the transcriptional regulatory sequence into the genome of the cell to activate protein expression in the cell. Therefore, at the very least, claims of Group III should be rejoined with claim 83 of Group I.

Furthermore, because the claims of Group I are directed to a method for making the product, and not to a method for using the product, the rationale for separating the cells of Group III from the methods of screening in Group II is not supported. The cells are not, in fact, being USED in materially different processes.

These arguments notwithstanding, Applicants respectfully assert that if the Examiner rejoins the claims of Group III to Group II, the burden of search will not change. Any search for the cell will inherently result in a search for the method of Group II. Any search for the method of Group II will inherently cover a search for the cell of Group III. Further, any search for the cell of Group III will inherently cover the process of claim 83 in Group I and any search of the process of claim 83 in Group I will inherently cover the cell of Group III.

Accordingly, Applicants request that Group III be rejoined to Group II and at least claim 83 of Group I. Applicants also request that, at least claim 83 of Group I be joined to the claims of

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Group II. Prosecution and pendency in this case would be greatly expedited without a duplication of time for the Examiner and expense for the Applicants.

Applicants believe that the application is in condition for allowance. Early notification in that regard is requested. If the Examiner believes that a telephonic interview would expedite prosecution of this case, he is invited to contact Applicants' attorney, Anne Brown at (216) 426-3586 or Cynthia L. Kanik at (617) 227-7400.

The Commissioner is hereby authorized to charge any fee deficiency to Deposit Account No. 12-0080, referencing Attorney Docket No. ATX-007CP4DV15CNRCE.

Respectfully submitted,



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